

510(k) Summary**JAN 11 2013**

Preparation Date 9 January 2013

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Trade Name: Sculptor Robotic Guidance Arm (RGA)

Common Name: Orthopedic Stereotaxic Instrument

Classification: 21 CFR 882.4560

Class II

Product Code OLO

Indications for Use The Sculptor Robotic Guidance Arm (RGA) is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The Sculptor RGA is indicated for use in unicompartmental knee replacement, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT-based model of the anatomy.

Device Description: Stanmore Implants Sculptor RGA utilizes a robotic arm to limit the surgeon's operation of a milling (cutting) tool to a safe area and a tracking arm to determine and monitor the location of the patient, providing dynamic referencing relative to the position of the robotic arm and the surgical plan; the device allows the surgeon to remove bone corresponding to the implant's shape as determined pre/intra-operatively.

Predicate Devices The Sculptor RGA is substantially equivalent to MAKO Surgical's Robotic Arm Interactive Orthopaedic System (K093425).

Technological Characteristics Compared to Predicate Device

Technological Characteristics	Stanmore Sculptor RGA	MAKO Surgical RIO (K093425)
Major Components	Robotic arm, tracking arm, drill system, Touch Screen Monitor	Guidance module, robotic arm, camera stand, drill system
Tools/Accessories	Cutting tools Bone interlock for tracking	Various probes, arrays tracked by optical camera
Images Used	CT	CT

Performance Data: Non Clinical Testing

Performance testing of the Sculptor RGA included the FDA recommended Electromagnetic Compatibility and Electrical Safety testing, and verification and validation testing for a software controlled device. Verification testing was performed to verify the Sculptor RGA registration process, software flow, and device safety. The following activities were verified:

- Touch screen calibration
- Software and hardware setup and shutdown procedures
- Individual hardware component function (e.g., Sculptor Arm, Tracking Arm)
- Correct interoperation of components
- Registration procedures
- Bone sculpting function and boundary data integrity
- Software thresholding, segmentation, data import, 3D model creation, joint and implant selection, landmarking, frames of reference, planning, workflow, patient file management, data integrity and backup, and CD burning
- System run-through

System level verification and validation testing was performed in the laboratory using Sawbone models to evaluate setup, registration, and overall accuracy and functionality of the system in supporting unicondylar knee replacement.

Clinical Case Series

Results from a prospective, single site, clinical case series of patients undergoing primary unicompartmental knee arthroplasty with a diagnosis of osteoarthritis demonstrate the ability of the Sculptor RGA to prepare the tibia and femur for accurate positioning of the components of a unicompartmental knee system. The case series involved 35 patients (36 knees) and included a radiographic assessment of implant placement, Oxford Knee Score outcomes, and quality of life assessment.

Assessments of lateral and A/P radiographs were performed by two orthopedic surgeons. Their analyses confirmed that the Sculptor accurately prepares the bone for unicompartmental knee replacement and validate the system's intended use.

**Substantial
Equivalence:**

Testing performed on this device indicates that the Sculptor RGA is substantially equivalent to the predicate device. Performance testing of the Sculptor RGA included the FDA recommended verification and validation testing. System level verification and validation testing was performed in the laboratory using Sawbone models to evaluate setup, registration, and overall accuracy and functionality of the system in supporting unicondylar knee replacement. A prospective, single arm clinical study conducted in the United Kingdom demonstrated good radiographic outcomes with respect to implant placement when the Sculptor RGA was used to prepare the bone for implantation.

Conclusion

The Sculptor RGA is shown to be substantially equivalent to previously cleared devices with respect to its intended use, indications for use, technological characteristics, and performance characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Stanmore Implants Worldwide, Limited
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January 11, 2013

Re: K121765

Trade/Device Name: Sculptor Robotic Guidance Arm (RGA)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 21, 2012
Received: December 26, 2012

Dear Ms. Rhodes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121765

Device Name: **Sculptor Robotic Guidance Arm (RGA)**

Indications for Use:

The Sculptor Robotic Guidance Arm (RGA) is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

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Prescription Use X

AND/ OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(Per 21 CFR 801 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen

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(Division Sign-Off)

Division of Surgical Devices

510(k) Number: K121765